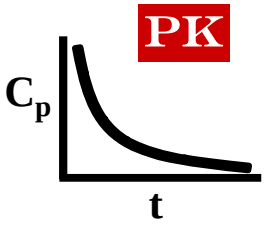
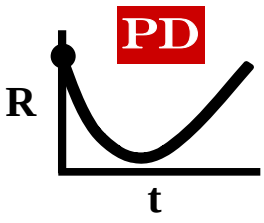
MAY 17-20, 2009: BUFFALO, NEW YORK

PHARMACOKINETIC-PHARMACODYNAMIC MODELING



Concepts and Applications



COURSE OUTLINE

Significant progress has been made in the theory and applications of *pharmacodynamics*. On the basis of diverse *pharmacokinetic-pharmacodynamic modeling* concepts it is possible to describe and predict the time course of drug effects under various physiological and pathological conditions. The study of pharmacokinetic-pharmacodynamic relationships can be of considerable value in understanding drug action, summarizing extensive data, building a knowledge repository, finding optimal dosing regimens, and in making predictions under new circumstances.

This course will deal with the theoretical aspects and with the applications of PK/PD modeling. Subjects that will be presented include:

"Thank you for the excellent PK/PD course. I really enjoyed the lectures and the "Pearls of Wisdom".
EGT May 2007

"The lectures were very educational, and fun too".
LZ May 2007

Basic pharmacodynamic theory: receptor binding, post-receptor events, and concentration-effect-time relationships.
Pharmacodynamic complexities: e.g. the role of distribution, metabolites, protein binding, animal scale-up; use of biomarkers and surrogate responses, models for pharmacogenomics.
Biophase compartment modeling: parametric and semi-parametric approaches.
Physiological pharmacodynamic modeling: indirect response models, cell lifespan models, chemotherapeutic effects.
Pharmacodynamic drug-drug interactions: isobolograms, competitive and non-competitive interactions.
Functional tolerance development: desensitization, counter-regulation, physiological feedback, indirect precursor models.
Population pharmacodynamics: application of NONMEM in pharmacodynamics, issues in use of covariates.
Specific drug applications: CNS active agents, cardiovascular agents, corticosteroids, anticoagulants, antibodies, antibiotics.
Special topics: Signal transduction, circadian rhythms, target-mediated PK/PD models, disease progression models.
Regulatory insights: use of pharmacometrics in drug approval and labeling.

COURSE DIRECTION

William J. Jusko, PhD

Dr. Jusko is Distinguished Professor and Chair of Pharmaceutical Sciences at the School of Pharmacy and Pharmaceutical Sciences at the University of Buffalo and Director of the Center of Excellence in Pharmacokinetics and Pharmacodynamics. Dr. Jusko supervises a research program on the pharmacokinetics and pharmacodynamics of immunosuppressive drugs such as corticosteroids, antidiabetic drugs, and holds two NIH grants in the areas of corticosteroid PK/PD and mathematical modeling. He has authored over 500 publications, consults for the FDA, NIH, and the pharmaceutical industry, and is listed in ISI Most Highly Cited in Pharmacology.


William J. Jusko, PhD

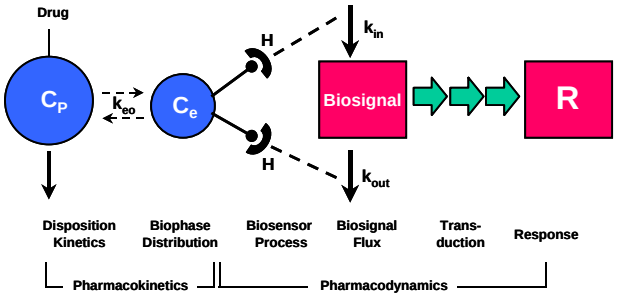
Ancillary Course A

May 14-16, 2009

Population PK/PD Modeling: Introduction to NONMEM®

A "hands on" computer tutorial.

NONMEM
COGNIGEN



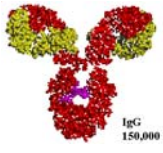
University at Buffalo
The State University of New York at Buffalo
School of Pharmacy and Pharmaceutical Sciences

Ancillary Course B

May 21-22, 2009

Monoclonal Antibody PK/PD

Dr. Joseph Baltasar



COURSE PROGRAM

May 17	**Sunday**
6:30-7:00	Registration/Reception
7:00-8:00	Dr. W.J. Jusko: **History & Highlights**
8:00-9:30	Dinner
May 18	**Monday**
08:00	Continental Breakfast
08:30-08:45	Dr. W.J. Jusko: **Introductions**
08:45-09:45	Dr. D. Mager: **Theory, Art, Practice of Modeling**
09:45-10:45	Dr. D. Mager: **Basic Pharmacology & Simple Effects**
10:45-11:00	Coffee
11:00-12:00	Dr. W.J. Jusko: **Modeling Biophase Distribution**
12:00-01:00	Lunch
01:00-02:00	Dr. W.J. Jusko: **Basic Indirect Response Models**
02:00-03:00	Dr. W. Krzyzanski: **Cell Lifespan Models**
03:00-03:30	Break
03:30-04:30	Dr. W.J. Jusko: **Complexities of Indirect Responses**
May 19	**Tuesday**
08:00	Continental Breakfast
08:30-09:45	Dr. D. Mager: **Review & Exercises I**
09:45-10:00	Coffee
10:00-11:00	Dr. W.J. Jusko: **Modeling Irreversible Effects**
11:00-12:00	Dr. D. Mager: **Modeling Transduction Processes**
12:00-01:00	Lunch
01:00-02:00	Dr. W.J. Jusko: **Modeling Functional Adaptation**
02:00-03:00	Dr. D. Mager: **Target-Mediated PK/PD Models**
03:00-03:15	Refreshments
03:15-04:15	Dr. W.J. Jusko : **Modeling Drug Interactions**
04:15-05:15	Dr. W.J. Jusko: **Animal Scaling in PK/PD**
May 20	**Wednesday**
08:00	Continental Breakfast
08:30-09:45	Dr. W.J. Jusko: **Review & Exercises II**
09:45-10:00	Coffee
10:00-11:00	Dr. J. Balthasar: **Monoclonal Antibodies**
11:00-12:00	Dr. W.J. Jusko: **Disease Progression Models**
12:00-01:00	Lunch
01:00-02:00	Pf. J. Fiedler-Kelly: **Population PK/PD Models**
02:00-03:00	Dr. J. Gobburu: **FDA & Pharmacometrics**
03:00-03:15	Refreshments
03:15-04:15	Dr. W.J. Jusko: **Computational Issues in PK/PD**
04:15-05:15	Dr. W.J. Jusko: **Final Discussion and Summary**

REGISTRATION INFORMATION

Course location: The course will be held at the Ramada Inn & Conference Center, 2401 N. Forest Road, Amherst, New York 14226-0823, U.S.A. Phone: (716) 636-7500. Fax: (716) 636-8296. The Conference Center is 15 min. from Buffalo International Airport. The price is $69/day. ***Hotel*** *Deadline: April 13, 2009.*

Fee: Individual fee: $2400. This includes course documentation, mid-session refreshments, lunches and opening dinner during the course. Up to 5 graduate students may enroll at a fee of $1200. US Government rate: $1800.

Registration: Please register ASAP in view of the limited course capacity of 40 participants. Confirmation of registration will be returned upon receipt, together with an invoice for the course fee. Registration will not be final until payment is received.

Cancellations: Cancellations with a full refund may be made until March 27, 2009. No refund is possible on cancellations received after this date. Substitutions may be made at any time.

Payment: University at Buffalo Foundation Inc. Bank transfers and credit card payments are accepted as well as checks. Course secretary: Rita Urben, (716) 645-2842 ext. 540.

Ancillary Antibody PK/PD Workshop: This course will be followed by an optional 2-day workshop on Monoclonal Antibody PK/PD by Dr. Joseph Balthasar. This course will utilize the facilities at the The University at Buffalo. An additional fee of $1600 is required (Govt. $1200, Students $800).

Ancillary NONMEM® Course: An optional 3-day hands-on tutorial course in "Population PK Data Analysis using NONMEM®" will be provided by Prof. Jill Fiedler-Kelly from Cognigen and Alan Forrest from UB. An additional fee of $2200 is required (Govt. $1600, Students $1100).

Niagara Excursion: Cognigen Corporation will sponsor a bus trip to Niagara Casino and Niagara Falls on Monday, May 18, at 5:30 PM.

REGISTRATION FORM: Pharmacokinetic-Pharmacodynamic Modeling, May 17-20, 2009.

NONMEM® , May 14-16, 2009.
Antibody PK/PD, May 21-22, 2009.

Name _____ **Title** _____ **Organization** _____
Address _____
City _____ **State/Country** _____ **Postal Code** _____
Telephone _____ **Fax** _____ **Email** _____

Opening Reception/Dinner, Sunday, May 17, 6:30 PM: _____Will Attend _____Will Not Attend Vegetarian Meal Requested _____
Excursion to Niagara Falls, Monday, May 18, 5:30 PM: _____Will Attend _____ Will Not Attend
Population PK (NONMEM®) Course: _____ Will Attend _____ Will Not Attend
Antibody PK/PD Workshop: _____ Will Attend _____ Will Not Attend

Signature _____ **Date** _____

Please return to: PK/PD MODELING, Department of Pharmaceutical Sciences, School of Pharmacy, State University of New York at Buffalo, 519 Hochstetter Hall, Buffalo, NY 14260; phone: (716) 645-2842, ext. 540; fax: (716) 645-3693; Email: rrurben@buffalo.edu